

REMARKS

I. Specification and Claim Amendments

Claims 39 and 44-47 are pending in the present Application. Claims 39 and 44-47 have been rejected under the provisions of 35 U.S.C. §103(a) as unpatentable over Harper (WO 00/44375) in view of Hamilton (US Patent No. 6,335,361) and Claims 39 and 44-47 have been rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claim 30 of co-pending Application No. 09/978,132.

The Specification has been amended to clarify the Title to the invention. Claim 39 has been amended to clarify the Claim and the rejection under 35 U.S.C. §103 has been overcome by pointing out the patentable distinction between the cited prior art and the present Claims.

All the Claims, including the amendments, are shown in a previous section of this Response. No new matter has been added. Support for the amendments is found in the Specification. Upon entry of this amendment, Claims 39 and 44-47 will be pending in the Application.

Reexamination and reconsideration of the Application as amended are respectfully requested.

II. The Rejection Under 35 U.S.C. §103(a)

Claims 39 and 44-47 have been rejected under the provisions of 35 U.S.C. §103(a) as unpatentable over Harper (WO 00/44375) in view of Hamilton (US Patent No. 6,335,361). This rejection is respectfully traversed.

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) set forth the test for determining obviousness under 35 U.S.C. §103(a). Determining obviousness requires four kinds of factual inquiries:

- (1) the scope and content of the prior art;
- (2) the differences between the prior art and the claimed invention;
- (3) the level of ordinary skill in the field of the invention; and
- (4) any objective indicia of success such as commercial success, long felt need, and copying.

See also, *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881, 45 U.S.P.Q.2d 1977 (Fed. Cir. 1998). In addition, when obviousness is based upon a combination of prior art references, there must be a showing of a suggestion or motivation to combine the teachings of those references. See *Gambro Lundia AB v. Baxter Corp.*, 110 F.3d 1573, 1579, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997) (The absence of such a suggestion to combine prior art

references is dispositive in an obviousness determination). *See also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582-83, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). Further, such a combination cannot be based upon "hindsight" that results from the use of applicant's own invention to justify the combination. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher"). Case law makes it clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (a teaching or suggestion or motivation to combine references is as an essential evidentiary component of an obviousness holding).

(1) The Scope and Content of the Prior Art

Harper discloses using vitamin E and vitamin C to overcome the problem of oxidative stress in a cat and dog, particularly oxidative stress that causes tissue damage, and to prevent or treat a disorder affected by oxidative stress.

Hamilton discloses using carnitine and lipoic acid to discourage age-related memory loss and provide improved memory in older individuals and others with unhealthy mitochondria. Hamilton states that:

Recent research has shown precisely how these compounds work to promote healthy mitochondria, which are the energy powerhouses of the cells. Mitochondria are responsible for the production of ATP and are present in relatively high numbers in essentially all cells of the body. The mitochondrial electron transport system consumes approximately 85% of the oxygen utilized by a cell. Cellular energy deficits caused by declines in mitochondrial function can impair normal cellular activities and compromise the cell's ability to adapt to various physiological stresses, a major factor in aging. Because of this high oxygen use, the mitochondria also have the highest production of oxidants.

(2) The Differences Between the Prior Art and the Claimed Invention

The present invention claims a method for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet by feeding the pet a mixture comprising

vitamin E, vitamin C, and at least one antioxidant selected from the group consisting of alpha lipoic acid, l-carnitine, and mixtures thereof.

The present invention differs from Harper in many respects. Harper discloses using vitamin E and vitamin C to overcome the problem of oxidative stress in a cat and dog and to prevent or treat a disorder affected by oxidative stress. The present invention, in contrast, claims a method for using vitamin E and vitamin C, in combination with at least one of carnitine and lipoic acid, to affect learning in aged pets. The present invention is not concerned with oxidative stress, particularly oxidative stress that is characterized by tissue damage. The mechanism for causing tissue damage due to oxidative stress is typically the result of excess free radicals. Vitamin E and vitamin C, however, have different mechanisms for altering biological functions. Vitamin E is a fat-soluble vitamin that acts as an antioxidant. The term "vitamin E" is used to refer to all tocol and trienol derivatives. The tocols are alpha-, beta-, gamma- and delta-tocopherols and the trienols are alpha-, beta-, gamma- and delta-tocotrienols. Vitamin E is an antioxidant but has more than one mechanism of action. While Vitamin E is known to destroy free radicals, vitamin E has been shown to stabilize membranes by physiochemical interaction between its phytol side chain and the fatty acid chain of polyunsaturated phospholipids. Vitamin E inhibits the synthesis of prostaglandins and prevents platelet aggregation in vitro and in vivo. Vitamin E also exhibits mechanisms of action in which its antioxidant role is not involved. Vitamin E succinate treatment of cancer cells (neuroblastoma) and normal fibroblasts (murine L-cells) inhibits prostaglandin (PG) E1- and PGA2- stimulated adenylate cyclase (converts ATP to adenosine 3', 5'-cyclic monophosphate) activity. This effect is primarily due to an inhibition of the catalytic protein activity of adenylate cyclase. Since the production of excess of prostaglandins is associated with suppression of the immune system and platelet aggregation, the mechanism involves stimulation of immunity and inhibition of platelet aggregation. Vitamin E also has a direct role in the regulation of gene expression by affecting transcription and translation. Similarly, Vitamin C (Ascorbic Acid) is a water soluble, white crystalline material that is stable in dry form. Vitamin C has many functions. Vitamin C functions as a coenzyme or as a cofactor in the body. In metabolism, vitamin C functions to accept and donate hydrogen. Vitamin C also plays an important role in the synthesis of neurotransmitters, i.e., compounds which allow nerve impulse transmission between nerve axons. Vitamin C is important and necessary for the synthesis of the neurotransmitters, norepinephrine and serotonin. It catalyzes

the conversion of dopamine to norepinephrine and the conversion of tryptophan to serotonin. Vitamin C plays a vital role in the formation of collagen by catalyzing chemical changes that allow lysine and proline to bind together as collagen subunits, adding structural stability to the "complete" collagen fibers. Vitamin C maintains capillary integrity through the production of an intercellular cement substance. This function promotes the healing of wounds, fractures, bruises, some hemorrhages, and bleeding gums. Additionally, Vitamin C reduces susceptibility to infections. Also, vitamin C helps to facilitate the absorption of iron and calcium. While both vitamin C and vitamin E are antioxidants, they have several mechanisms of action. The present invention is clearly distinguishable from Harper because Harper is concerned with the mechanism of action of the compounds that overcomes the problem of oxidative stress. The present invention uses the compounds, in combination with other compounds, to affect learning in aged pets.

Further, there is nothing in Harper that indicates that the compounds have any particular effect in aged animals or that they have any effect on learning. Harper administers the compounds to overcome the problem of oxidative stress and related tissue damage in animals of any age. The age of the animal is not important in Harper; the present invention claims affecting learning in aged animals. Also, there is nothing in Harper that relates to affecting learning, particularly nothing that indicates that oxidative stress is related to learning.

Similarly, Harper requires a method for increasing the plasma vitamin E level by incorporating higher levels of vitamin E in the animal's diet. The present invention, particularly Claims 46 and 47, use normal levels of these compounds but use them in combination with other compounds to affect learning.

The present invention is distinguishable from Hamilton in several respects. While the present invention feeds carnitine and/or lipoic acid to the pet, the invention claims a method for inhibiting the loss of learning ability or increasing learning ability. Hamilton, in contrast, teaches using carnitine and lipoic acid to discourage age-related memory loss and provide improved memory. While memory and learning may be somewhat related, they are distinct mental functions. Memory involves the ability to recall previously learned or observed events. Learning involves the ability to perceive and assimilate facts, patterns, or observed events. Also, memory involves registering, retaining, storing, and retrieving information previously exposed to,

generally via an event or experience. Learning is the acquisition and/or encoding of new information through experience or practice.

Further, Hamilton teaches using both compounds for their combined affect. While the use of both compounds is claimed in one embodiment of the present invention, the compounds function independently and can be used alone.

Similarly, Hamilton teaches using carnitine and lipoic acid to "discourage age-related memory loss and provide improved memory in older individuals and others with unhealthy mitochondria." The present invention, in contrast, administers carnitine and/or lipoic acid, in combination with vitamin E and vitamin C, to affect learning. There is nothing to correlate mitochondria (the cell's energy plant) with learning. Indeed, healthy individuals with functioning mitochondria are capable of learning and there is nothing to indicate that improving mitochondria function improves (or impairs) learning.

(3) The Obviousness Determination

It is well established that there must be some teaching in the references which would provide a motivation or logical reason to a person of ordinary skill in the art to combine the teachings of the references. See *W.L. Gore and Associates v. Garlock*, 220 U.S.P.Q. 303 (Fed. Cir. 1983) and *A.S.C. Hospital Systems, Inc., v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). Basically, the question in the present case is whether a fair reading of two separate and demonstratively different references as a whole would suggest such a combination to one of ordinary skill in the art at the time of the invention.

There is simply no teaching in any of the references that would motivate anyone to combine patents that teach the use of (1) vitamin E and vitamin C to overcome the problem of oxidative stress, particularly oxidative stress induced tissue damage, in a cat and dog of any age and (2) carnitine and lipoic acid to discourage age-related memory loss and provide improved memory in older individuals and others with unhealthy mitochondria to achieve the present invention. The present invention claims the use of vitamin E, vitamin C, and/or carnitine and lipoic acid to affect learning in aged pets. There is nothing in the references to teach or motivate their combination to conclude that compounds that affect memory will also affect learning. Similarly, there is nothing in the references to teach or motivate their combination to conclude that there is any association between oxidative stress and learning in aged pets. Further, there is

nothing in the references to teach or motivate their combination to conclude that compounds that affect mitochondria will have any affect on learning.

Basically, the Examiner has taken two references, one that teaches using vitamin E and vitamin C to overcome problems with oxidative stress and one that teaches using lipoic acid and carnitine to improve memory in older animals with unhealthy mitochondria, and concluded that an invention that uses vitamin E and vitamin C in combination with one or both of lipoic acid and carnitine to affect learning is obvious. The Examiner can have reached this conclusion only through the impermissible use of hindsight. The two references when combined disclose the use of the compounds of the present invention for different functions, e.g., fight oxidative stress and improve memory. However, there is nothing in the references that teach or motivate one to conclude that they can be used in combination to affect learning. Only after reviewing the present invention would one conclude that any of the compounds disclosed in either reference could be used to affect learning.

The cited references provide no teaching that would motivate one to combine the references to achieve the present invention. i.e., combine the references relating to using vitamin E and vitamin C to overcome the problem of oxidative stress in a cat and dog and using carnitine and lipoic acid to discourage age-related memory loss and provide improved memory in older individuals and others with unhealthy mitochondria to teach a method for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet. The rejection under 35 U.S.C. 103(a) is therefore improper and should be withdrawn.

III. The Obviousness-type Double Patenting Rejection

Applicant requests clarification of the rejection. Co-pending Application No. 09/978,132 was published as US Patent Application No.20020119182 on August 29, 2002. The published Application contains 29 claims. The Application issued as US Patent No. 6,914,071 on July 05, 2005. The patent contains 11 claims.

The rejection is based on Claim 30 of co-pending Application No. 09/978,132, which only contains 29 Claims. Clarification is requested.

Applicant contemplates filing a Terminal Disclaimer, if justified, based on US Patent No. 6,914,071 once the rejection is clarified.

IV. Conclusion

In summary, the rejection under 35 U.S.C. §103 has been obviated or overcome. In view of the foregoing Remarks, it is submitted that the Claims are in condition for allowance. Reexamination and reconsideration of the Application as amended is requested and allowance of the Claims at an early date is solicited.

If the Examiner believes that personal communication will expedite prosecution of this Application, the Examiner is invited to call the undersigned at the number listed below.

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